

nisms. The objective of the present study was to confirm the existence of this psychological adaptation capacity in chronic patients as kidney transplant bearers. **METHODS:** We studied the Erectile Dysfunction (ED) using the IIEF-5, and the HRQOL, using the SF-36 Health Survey, in all renal transplant patients of our region ($n = 242$), searching for the influence of ED over the HRQOL of these patients. **RESULTS:** Included patients = 199 (82%); Excluded patients = 44. Median age was 52 yrs. (43–62); 106 patients (54.9%) presented ED measured by a IIEF-5 score ≤ 21 points. Severity of ED was as follows: severe ED = 20.7%, moderate ED = 10.9%, mild to moderate ED = 11.4%, mild ED = 11.9% and no ED = 45.1%. These patients were separated into 4 groups according to median age and quartiles: ≤ 42 years (group1); 43 to 51 (group2); 52 to 61 (group3); and ≥ 62 (group4). SF-36 scores were worse for ED patients in the 3 first age groups, but not in the aged group 4. These differences between patients with ED and patients without ED were statistically significant in age groups 2 and 3, mainly in physical areas: Group 1, Bodily Pain; Group 2, General Health and Physical Component Summary score (PCS); Group 3, Rol Physical, Vitality and PCS. SF-36 Mental Component Summary (MCS) was similar for patients with ED and patients without ED in all age groups. **CONCLUSIONS:** Opposite to commonly accepted, we confirmed the hypothesis that a mental adaptation occurs in chronic patients as the studied subjects. Association found of ED with PCS and other dimensions of physical area could be explained with the intermediate influence of other variables.

PWM5**PRELIMINARY VALIDATION OF A NEW DISEASE-SPECIFIC UTILITY MEASURE FOR ERECTILE DYSFUNCTION**

Torrance G¹, Keresteci M², Breton M³, Ryan N²

¹McMaster University/Innovus Research Inc, Burlington, ON, Canada; ²Innovus Research Inc, Burlington, ON, Canada;

³Pfizer Canada Inc, Kirkland, QC, Canada

OBJECTIVE: The objective was to combine, in one, paper-based, self-completion instrument, the strengths of two approaches to assessing health-related quality of life: the sensitivity and relevance of the disease-specific approach and the generalizability and decision support power of the utility approach. The instrument was developed for erectile dysfunction (ED). **METHODS:** The instrument has two linked stages, each with a visual analog scale (VAS). VAS1 measures preferences for the patient's self state and for disease marker states. VAS2 measures preferences on the traditional dead-healthy 0–1 scale. The instrument was used in a double-blind, placebo-controlled, 12-week clinical trial ($n = 169$). At subject recruitment, it was administered twice, one week apart. All results reported here are based on that data, except responsiveness, which is based on the 12-week data for both treatment groups combined. **RESULTS:**

Feasibility: Completion rates were approximately 90% overall and approximately 95% for key data. Error rates were 2%. Most patients required minimal or no assistance. **Reliability:** One-week, test-retest reliabilities of all preference scores, as measured by intra-class correlation, were strong (>0.50). The key score, self-state on VAS2, had the highest reliability (0.70). **Face validity:** Scores were ranked in the expected order. **Discriminative validity:** Self-state scores were positively and statistically significantly correlated with disease severity. Pearson correlation coefficients were 0.37 on VAS1, 0.24 on VAS2. **Responsiveness:** Change over 12 weeks in self-state scores were positively and statistically significantly correlated with change in disease severity. Spearman correlation coefficients were 0.44 on VAS1, 0.37 on VAS2. **CONCLUSIONS:** We have developed a preference-based, disease-specific instrument for ED. The instrument provides preference scores for the patient's self state and for clinical marker states on a disease-specific scale and on the traditional 0–1 dead-healthy generic scale. The performance of the instrument in this initial application was encouraging. The instrument demonstrated feasibility, reliability, validity and responsiveness.

WOMEN'S AND MEN'S HEALTH—Quality of Life/Preference**PWM6****POST-MENOPAUSAL HORMONE THERAPY: DO HYPERTENSION AND THROMBOPHILIA MATTER?**

Marchetti M, Barosi G

IRCCS Policlinico S.Matteo, Pavia, Italy

OBJECTIVES: Estro-progestinic substitutive therapy (HRT) showed to increase breast cancer incidence, if the therapy is prolonged over five years, and cardiovascular events in some subsets of patients (HERS trial), nevertheless it protects against colon cancer and osteoporosis. Thrombophilia might mediate the adverse cardiovascular effect of HRT. **METHODS:** We used a parametric Markov model to shape health states and events (breast cancer, colon cancer, venous thromboembolism, biliary cholic, bone fractures, myocardial infarction). Quality of life depended on both the modeled health states/events, but also on menopause symptoms. Decision analysis (DATA 4.0, TreeAge) assessed the impact of screening for unknown thrombophilia (factor V Leiden, prothrombin G20210A, hyperhomocysteinaemia) on life expectancy (LE) and quality-adjusted life expectancy (QALE). **RESULTS:** Screening for thrombophilia all the post-menopausal women does not lead to an increment of QALE, that remains 28.05 quality-adjusted life years (QALYs). However, screening is warranted in hypertensive women since those who carry either the prothrombin mutated gene or two Leiden mutated factor V genes do better to avert HRT since this allows the population

to gain 0.5 QALYs. Screening is warranted in hypertensive women despite a high predisposition to breast cancer: the overall gain of screening in this subset is 0.8 QALYs. Those women who carry both factor V and prothrombin mutations should stop HRT after 4.2 years. Multiple-ways sensitivity analysis showed that in women with no thrombophilia the risk of coronary disease or breast cancer do not influence the utility of HRT, while the risks are fundamental in deciding whether to treat women with multiple thrombophilic defects. Thus, family and personal history and post-menopausal symptoms do not define a risk profile that can really optimize HRT prescription in all the patient subsets. **CONCLUSIONS:** According to the available evidence, screening for thrombophilia is not helpful in all candidates for HRT, however, specific risk profiles should prompt the screening as to allow for a specific optimization of HRT prescription and duration.

PWM7

USING A DISCRETE CHOICE EXPERIMENT TO VALUE AN INJECTION DEVICE FOR INFERTILITY TREATMENT

Brown RE¹, Ryan M², Johannes E³, Pechevis M⁴, Chevat C⁵

¹MEDTAP International, London, UK; ²University of Aberdeen, Aberdeen, United Kingdom; ³Organon, Oss, Netherlands;

⁴Cemka, Bourg-la-Reine, France; ⁵Organon, France, Puteaux, Cedex, France

OBJECTIVES: Determine the value of the Puregon Pen compared to the standard syringe treatment for women undergoing infertility treatment. **METHODS:** A discrete choice experiment (DCE) was developed and piloted on 18 women experienced with gonadotrophin injections with the standard syringe. Based upon responses, the instrument was revised and after obtaining informed consent, administered by nurses to a convenience sample of 60 women with 1 or 2 prior cycles of injected gonadotrophins for infertility treatment in 6 participating clinics in France. Attributes in the DCE were "local skin reactions" and "cost". Based on these attributes respondents were asked to choose between "continuing with the syringe" or "switching to the Pen". The experiment used an orthogonal in difference design and each subject was presented with 15 choices. Given cost was included as an attribute willingness to pay for both the syringe and pen could be estimated. Information was also collected on demographics and pain, anxiety and fear of syringe injections. **RESULTS:** There were 50 evaluable respondents. Average age was 33; 69% had 1 previous cycle of infertility treatment, 62% had injections at home by a nurse and 18% self-injected. 29% indicated the injections were always or usually painful and 62% feared the injection would not be done properly if self-injected. The discrete model analysis indicated a general preference for the Pen over the syringe and a WTP of €56. **CONCLUSION:** Women were capable of choosing between the Pen and syringe and from this WTP for the different treatment

options was estimated. Based on these results, women prefer the Pen over the syringe.

WOMEN'S AND MEN'S HEALTH—Healthcare Policy

PWM8

ASSOCIATION BETWEEN PATERNAL EXPOSURE TO SOLVENTS AND SPONTANEOUS ABORTIONS

Logman JFS¹, de Vries LE¹, Hemels M¹, Khattak S², Einarson T¹

¹University of Toronto, Toronto, ON, Canada; ²Biopharmatrials Inc, Whitby, ON, Canada

OBJECTIVE: Several studies have presented conflicting reports concerning the relationship between paternal organic solvent exposure and spontaneous abortions (SAs). We conducted a meta-analysis to evaluate and quantify that risk. **METHODS:** A literature search was performed on Medline, Toxline, and Embase. We searched for all original comparative research studies, published from 1966 to the present (AP 2002), that investigated pre- and periconceptional paternal organic solvent exposure and subsequent SA. Two independent reviewers identified and extracted the data; disagreements were resolved by consensus. The Mantel-Haenszel method was used to calculate summary odds ratios (ORs) with 95% confidence intervals (CI). Homogeneity of effects was assessed using chi-square and a funnel plot was used to examine publication bias. **RESULTS:** Forty-four studies were identified; 39 were excluded (13 examined inappropriate exposures, 12 had inappropriate outcomes, 9 were reviews, 4 had no extractable data, 1 was a duplicate). Five studies provided useable data, but the exposure assessment varied considerably. Some studies used only occupational codes, while others conducted telephone interviews to insure actual exposure. For the 3 case control studies with confirmed high exposure to solvents ($n = 91,550$), ORs = 1.26 (CI 95%: 0.80–1.99). Power was 87.8%. When all available data ($n = 18,800$) were combined, ORs = 1.19 (CI 95%: 1.04–1.35), but effects were heterogeneous (Chi-square = 56.74, $p < 0.001$) and the funnel plot displayed publication bias, as there were no small negative studies. After adjusting for bias, significance disappeared (ORs = 0.98, 0.90–1.08). **CONCLUSION:** The risk for spontaneous abortion is not increased by the paternal occupational exposure to organic solvents. Selective publication of small positive studies may have falsely exaggerated this risk.